



Direct Healthcare Professional Communication

December 2021

Octreotide Solution for Subcutaneous injection and intravenous infusion: Risk of atrioventricular block

Dear Healthcare Professional,

The Egyptian Pharmaceutical Vigilance Center of the Central Administration for Pharmaceutical Care at The Egyptian Drug Authority would like to inform you of the following:

Summary

- Atrioventricular blocks (including complete atrioventricular block) were reported in patients receiving high doses of continuous infusion (100 micrograms/hour) and in patients receiving bolus octreotide intravenously (50 micrograms bolus followed by 50 micrograms/hour continuous infusion). The maximum dose of 50 microgram/hour should therefore not be exceeded.
- Patients who receive high doses of intravenous octreotide should be kept under appropriate cardiac monitoring.
- Octreotide may lower your heart rate and at very high doses may cause abnormal heart Rhythm. Your doctor may monitor your heart rate during treatment.

Background information on the security concerns

- Octreotide is indicated for Symptomatic control and reduction of growth hormone (GH) and IGF-1 plasma levels in patients with acromegaly who are inadequately controlled by surgery or radiotherapy. Sandostatin is also indicated for acromegalic patients unfit or unwilling to undergo surgery, or in the interim period until radiotherapy becomes fully effective.
- For the relief of symptoms associated with the following functional tumours of the gastro-entero-pancreatic endocrine system:
 - carcinoid tumours with features of the carcinoid syndrome
 - vasoactive intestinal peptide secreting tumours (VIPomas).
- For reduction of the incidence of complications following pancreatic surgery.
- Sandostatin is not an anti-tumour therapy and is not curative in these patients.

Prevention of complications following pancreatic surgery.

Emergency management to stop bleeding and to protect from re-bleeding owing to gastro-oesophageal





varices in patients with cirrhosis. Sandostatin is to be used in association with specific treatment such as endoscopic sclerotherapy.

Treatment of TSH-secreting pituitary adenomas:

- when secretion has not normalised after surgery and/or radiotherapy;
- in patients in whom surgery is inappropriate;
- in irradiated patients, until radiotherapy is effective.

References

TGA

<https://www.tga.gov.au/publication-issue/octreotide-and-atrioventricular-block>

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions via the Egyptian reporting system:

Name: Egyptian Pharmaceutical Vigilance Center

Address: 21 Abd El Aziz Al Soud Street, El-Manial, Cairo, Egypt, And PO Box: 11451 Telephone: +202- 25354100, Extension: 1470 Fax: +202 – 23610497

Email: pv.followup@edaegypt.gov.eg

Online reporting: <https://primaryreporting.who-umc.org/EG>

QR Code:

Hotline: 15301

